ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE 2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515–6115

> Majority (202) 225–2927 Minority (202) 225–3641

June 29, 2011

Mr. John Ducker, President and CEO APP Pharmaceuticals, LLC 1501 East Woodfield Road, #300 East Schaumburg, IL 60173

Dear Mr. Ducker:

We are writing to request your assistance and cooperation on a matter of great importance to our Committee.

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee since February 23, 2011, has been investigating the contamination of the U.S. supply of heparin (a blood-thinning drug administered to approximately 12 million individuals in the U.S. annually), and the adequacy of investigations of the heparin matter. It has been more than three years since the Food and Drug Administration (FDA) linked several patient deaths and serious allergic-type reactions of patients in the United States to supplies of heparin that came from the People's Republic of China which was adulterated with overly sulfated chondroitin sulfate (OSCS). Officials of the FDA have concluded that this was an instance of economically motivated adulteration. However, neither the Chinese government nor the FDA has identified those responsible for the contamination or described how the heparin actually came to be contaminated.

We believe there is substantial public interest in solving this case. More than 80 percent of the U.S. unfractionated heparin supply is sourced from China and more than 16 percent of U.S. pharmaceutical ingredients are imported from China. There is reason to believe all or some of the individuals responsible for the adulteration are still actively engaged in the Chinese pharmaceutical supply chain and pose a continuing threat to pharmaceutical products imported to the U.S. How the heparin came to be contaminated and the exact nature of the contaminant remain unknown. It is important to determine how the adulteration happened so that industry and government can take more effective proactive measures to reduce the risk of such adulteration in the future.

We are writing to you because documents provided by the FDA indicate that your company has information related to the Chinese heparin industry and Chinese heparin supply chains. This information would be helpful to our inquiry on the contamination of the heparin supply. Because your company has such information, please provide the following by July 29, 2011. The relevant time period for the following requests is January 1, 2006, to the present.

- 1. All documents relating to heparin-related firms in China.
- 2. All documents relating to the adulteration of the U.S. heparin supply or the adulteration of heparin supplies in countries other than the U.S. Adulteration would include substitution or partial substitution of porcine heparin with heparin from other animal sources.
- 3. All documents relating to oversulfated glycoaminoglycans.

The Committee staff would be happy to discuss the nature of the information requested and the manner of production. An attachment to this letter provides information on how to respond to the Committee's request.

If you have any questions regarding this request, please contact Alan Slobodin with the Committee staff at (202) 225-2927. Your assistance and cooperation is greatly appreciated.

Sincerely,

Pred Upton Chairman Joe Barton

Chairman Emeritus

Cliff Stearn

Chairman

Subcommittee on Oversight and

and Investigations

Joseph R. Pitts

Chairman

Subcommittee on Health

Michael C. Burgess

Vice Chairman

Subcommittee on Health

Attachment

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member Subcommittee on Oversight and Investigations

The Honorable Frank Pallone, Jr., Ranking Member Subcommittee on Health